UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,599	02/12/2001	Wouter E. Roorda	M-9246 US	3819

7590 06/30/2003

Cameron Kerrigan
Squire Sanders & Dempsey LLP
One Maritime Plaza
Suite 300
San Francisco, CA 94111-3492

EXAMINER	
PULLIAM, AMY E	

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/781,599	Applicant(s) ROORDA ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11-13,21,22,24,25,27 and 29-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11-13,21,22,24,25,27 and 29-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Extension of Time and the Amendment A, both received by the Office April 9, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11-13, and 21, 22, 24, 25, 27, and 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,879,713 to Roth *et al.*. Roth *et al.* teach targeted delivery via biodegradable polymers, more specifically to provide a means for locally administering bioactive molecules to tissues or cells in a patient in a controlled, sustained manner (abstract, and column 2, lines 49-52). Roth *et al.* teach that the polymeric carrier is in the form of microparticles that are targeted by size and degradation and release properties to particular regions of the body, especially the alveoli and capillaries (column 3, lines 22-26). Roth *et al.* also teach that microparticles with specific diameters are selected to lodge in particular regions of the body, such as in a capillary (column 7, lines 33-40). Angiogenic factors are listed as possible biologically active agents which can be incorporated in the polymeric carrier , i.e., within microparticles which are immobilized in the carrier (column 9, lines 60-64). Roth *et al.*

also teach that the microparticles can be administered once, or may be divided into smaller doses to be administered at varying intervals of time, depending on the release rate of the particle, and the desired dosage (column 13, lines 41-44). Furthermore, Roth *et al.* teach that the microparticles selectively lodge at the targeted site within the vascular system of the animal where release is desired for a sufficient amount of time to permit controlled release of a therapeutically effective amount of the biologically active molecules (column 17, claim 1).

Roth *et al.* do not specifically teach that the particle be embolized for less than one week. However, Roth *et al.* do state that the microparticle should lodge for a sufficient amount of time to permit controlled release of the active agent. It is the position of the examiner that one of ordinary skill in the art would consider the time a manipulatable parameter, depending upon the active agent used and the desired effect.

Additionally, Roth *et al.* do not specifically teach that the particle should be placed above, below or in between the occlusions or blocks in the vessels. However, it is the position of the examiner that this is not a patentable distinction. The purpose of the Roth disclosure is to deliver biologically active agents to a targeted site in the vascular system wherever treatment is needed. Furthermore, Roth *et al.* achieve the same result as that sought by applicant, which is the vascularization or the target area. Absent evidence to the contrary, it appears that the particulars as to whether the microparticles are introduced below or above the occlusion does not render patentable distinction to the claim. Any evidence provided to rebut this statement must be shown to depend solely on the actual placement of the microparticles with respect to the occlusion.

It is the position of the examiner that the teachings of Roth *et al.* render applicant's instant claims obvious. One of ordinary skill in the art would have been motivated, by the teachings of Roth *et al.*, to introduce microparticles containing angiogenesis factors, into the vascular system, in an effort to deliver the active agent at a targeted site, and therefore increase vascularization. The expected result would be successful targeted delivery of an active agent. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that Roth dails to disclose that their microparticles are capable of forming emboil for a duration that is less than the duration which results in cell damage or cell death. Applicant further argues that Roth *et al.* do not recognize the problem of cell damage. Based on these arguments, Applicant concludes that the microparticles of Roth are therefore incapable of degrading in less than seven days. The examiner disagrees with this assumption for the following reasons.

First, it is discussed in the obviousness rejection that Roth *et al.* do not discuss the specific time period the microparticles are to remain lodged. The examiner, however, pointed to a particular passage of Roth *et al.*, which states that the Roth microparticles are to remain lodged for a sufficient period of time to permit controlled release of a therapeutically effective amount of the active molecules. This generic teaching impliedly discloses several underlying ideas. First, Roth *et al.* acknowledge that there is a point at which the microparticles are to no longer

remain lodged. Second, the exact time for the microparticles to remain lodged will depend on the particular active agent being employed and the specific effect desired. Third, the time is obviously manipulatable, as Roth *et al.* broadly teach that the microparticles will remain lodged for a "sufficient amount of time," implying that this time can easily be altered to suit the desired needs.

The second reason the examiner disagrees with Applicant's assumption that Roth's microparticles are incapable of degrading in less than seven days is that there has been no evidence provided to support this conclusion. The teachings of Roth *et al.* suggest the limitations of Applicant's instant claims and achieve the same desired effect. In order to be persuasive, this conclusory statement, that Roth's microparticles are incapable of degrading in less than seven days, must be provided in Declaration form, with experimental data supporting the conclusion.

Additionally, it is the position of the examiner that when one skilled in the art is performing a method to achieve a therapeutic effect, it would be obvious to the skilled artisan to prevent cell damage and cell death. These are not limitations which are generally found necessary to incorporate into claim limitations. One would assume that when providing a therapeutic affect, said method is performed so as to prevent cell damage and cell death, while achieving the desired effect.

The teachings of Roth *et al.* achieve the same affect as the method claimed by Applicant. Applicant is attempting to differentiate between the two based upon the time the microparticle is lodged. However, there is nothing in the instant claims which specifies what causes this alleged

difference. It is recommended that the limitations which cause this difference in time be incorporated into the claim language.

Additionally, it is the position of the examiner that there has been nothing discussed to explain any difference in transitory time between the cited reference and the instant claims. For example, the reference teaches that the microparticles may have sizes than range from 0.2 to 100 microns, but more particularly 10-25 microns, and most preferably 15-20 microns (c 7, l 39-45). Similarly, the instant claims teach that the particles are between 10 to 50 microns. Therefore, Roth *et al.* teach the same particles, with the same size, to be used in the same manner, and one skilled in the art would expect the particles to behave in the same was. Additionally, Roth *et al.* teach that their formulation is biodegrable, and therefore the limitations drawn to the microparticle degrading to a smaller diameter is obvious. Lastly, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For the above reasons, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. E. Pulliam
June 27, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600